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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,131	04/19/2004	Daniel Gaudet	WIBL-P02-522	2809

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,131	GAUDET ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachment I & II*.

DETAILED ACTION

1. Claims 1-24 are pending.

2. Applicant's election of the species 'an isolated nucleic acid comprising a portion of SEQ ID NO:3 wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase gene' in the reply filed on 05/29/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-24 are currently under examination as they read on an isolated nucleic acid of SEQ ID NO:3.

4. Applicant's IDS document filed on 04/19/2004 is acknowledged.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 5-6, 12-13, 15-16 and 22-24 recite specific mutant alleles by nucleotide residues without reference to a specified sequence identification number makes the claims indefinite. A reference sequence identification number with the exact position within the sequence to be mutated (in the instant claims nucleotide position 51 of SEQ ID NO:3) for each claimed mutant showing exactly where the mutants are different from the reference sequence would make the claims definite. The instant claims encompass all nucleic acids comprising any 10 nucleotide or more portion of SEQ ID NO:3 (need not be consecutive) that includes any mutant at position 29 of exon 10 of any glycerol kinase gene from any organism, including all as yet undiscovered variants. The recitation of position 29 of exon 10 within all variants is indefinite without a reference sequence to which it refers.

The recitation of "an isolated nucleic acid which specifically hybridizes to a portion of SEQ ID NO:3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29" in claim 22 is ambiguous. Although the specification discloses general parameters for calculating such conditions, in the absence of a clear definition of the metes and bounds of this phrase it is unclear which conditions are actually claimed. It is suggested that Applicant amend the claims to recite a particular set of hybridization and wash conditions to overcome this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: an isolated nucleic acid molecule consisting of a 10 or more consecutive nucleotide portion of SEQ ID NO: 3 that includes nucleotide position 51 and an isolated nucleic acid molecule consisting of SEQ ID NO: 3, does not provide reasonable enablement for: an isolated nucleic acid molecule comprising a **portion of SEQ ID NO: 3**, wherein **said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene**, and wherein said nucleic acid molecule **comprises a mutant allele of said GK gene at said nucleotide position 29** of claim 1; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule **comprises a portion of SEQ ID NO: 3**, wherein **said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene**, and wherein said nucleic acid molecule comprises **a mutant allele of said GK gene at said nucleotide position 29** of claim 2; The nucleic acid molecule of claim 1, wherein **said portion is at least 20 nucleotides in length** of claim 3; The nucleic acid molecule of claim 1, wherein **said portion is at least 50 nucleotides in length** of claim 4; The nucleic acid molecule of claim 1, wherein said mutant allele **comprises a nucleotide selected from the group consisting of a guanosine, a thymidine, and a cytidine at**

said nucleotide position 29 of claim 5; The nucleic acid molecule of claim 5, wherein said nucleic acid molecule comprises a **guanosine at said nucleotide position 29** of claim 6; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and **polypeptide nucleic acid (PNA)** of claim 7; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule comprises a label of claim 8; The nucleic acid molecule of claim 8, wherein the label is selected from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 9; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is immobilized on a solid support of claim 10; The nucleic acid molecule of claim 10, wherein the nucleic acid molecule is one of an array of **two or more different nucleic acid molecules** immobilized on said solid support of claim 11; An isolated nucleic acid molecule **comprising** SEQ ID NO: 3, wherein said nucleic acid molecule **comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene** of claim 12; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule **comprises SEQ ID NO: 3**, wherein said nucleic acid molecule **comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene** of claim 13; The nucleic acid molecule of claim 12, wherein said nucleic acid molecule is at least 250 nucleotides in length of claim 14; The nucleic acid molecule of claim 12, wherein said mutant allele comprises a nucleotide selected from the group consisting **of a guanosine, a thymidine, and a cytidine at said nucleotide position 29** of claim 15; The nucleic acid molecule of claim 15, wherein said nucleic acid molecule comprises **a guanosine at said nucleotide position 29** of claim 16; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and **polypeptide nucleic**

acid (PNA) of claim 17; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule comprises a label of claim 18; The nucleic acid molecule of claim 18, wherein the label is selected from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 19; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule is immobilized on a solid support of claim 20; The nucleic acid molecule of claim 20, wherein the nucleic acid molecule is one of an array of **two or more different nucleic acid molecules** immobilized on said solid support of claim 21; An isolated nucleic acid molecule which **specifically hybridizes to a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon l0 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29** of claim 22; An isolated nucleic acid molecule consisting of **a portion of SEQ ID NO: 3**, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 of claim 23; and An isolated nucleic acid molecule consisting of SEQ ID NO: 3, wherein said nucleic acid molecule comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene at said nucleotide position 29 of claim 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not provide a sufficient enabling description of the claimed invention. The specification discloses only a single nucleic acid sequence consisting of SEQ ID NO:3.

The specification does not adequately disclose any nucleic acid "comprising" "a portion" of SEQ ID NO:3. The term "comprising" is open-language which opens the claims up to read on any nucleic acid with 10 nucleotides of SEQ ID NO:3 with any number of additional nucleotides in the nucleic acid or up to 10 or 40 undisclosed nucleotides in claims 3 and 4. Further, Claim 14 recites at least 250 nucleotides in length, however, SEQ iD NO:3 is only 94 nucleotides in length, the skilled in the art would not know the unspecified at least 160 nucleotides in the nucleic acid. Also, the term "portion" is not limited to a consecutive 10 nucleotide portion of SEQ ID NO:3, as it just recites a portion. 10 scattered nucleotides of SEQ ID NO:3 in any order is still a portion that is 10 nucleotides.

Further and as discussed above a nucleic acid comprising position 29 of exon 10 is not adequately disclosed in the specification. Since the nucleic acid of the instant application as claimed need only comprise that nucleic acid at position 29 of exon 10 in any location within the nucleic acid and the nucleic acids may be any nucleic acid, then essentially all nucleic acids are encompassed by the instant claim language and there is insufficient guidance in the specification as to which nucleic acids will work in the claimed invention.

It was well known in the art at the time the invention was made that hybridization could occur between two sequence based upon short stretches of 100% identity. Further, hybridization under conditions other than high stringency would be expected to permit a great deal of variation between the two hybridizing sequences. The term "comprising" is open-ended and expands the nucleic acid portion of SEQ ID NO: 3 to include additional undisclosed nucleic acids outside of the portion of SEQ ID NO:3. The prior art, including Meinkoth et al., teaches that many factors affect nucleic acid hybridization, such as probe length of the shortest chain in the duplex, ionic strength, base composition and concentration of the helix destabilizing agents (PTO-892, Reference U; In particular, page 269, left column 2nd and 3rd paragraphs). Therefore, a nucleic acid which hybridizes to a nucleic acid "comprising" a portion of SEQ ID NO:3 may actually be hybridizing to regions outside of the portion of SEQ ID NO:3 and not have to do with the nucleic acid sequence of SEQ ID NO:3 at all. In the same way, hybridization under any other conditions than stringent conditions may allow hybridization of sequences of less than 100% similarity. Finally, as taught by Meinkoth et al., sequences of less than 100% similarity, as is the instant

case with one nucleic acid difference, may still hybridize, making a complementary DNA to a portion of SEQ ID NO:3 including the mutant allele not effective for screening.

The specification has also not adequately disclosed any array of two or more nucleic acids immobilized onto a solid support. The second nuclei acids molecule can be any nuclei acids molecule and the specification has not adequately disclosed the genus of all of the claimed arrays.

The specification has also not adequately disclosed a nucleic acid of the instant invention that is a polypeptide nucleic acid (PNA), as encompassed in claims 7 and 17.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the instantly recited nucleic acid sequences and still encode a polypeptide that maintains the functional properties of the polypeptide of SEQ ID NO:1 is unpredictable, as is the identity of which subsequences would encode a functional polypeptide; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

9. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : an isolated nucleic acid molecule consisting of a 10 or more consecutive nucleotide portion of SEQ ID NO: 3 that includes nucleotide position 51 and an isolated nucleic acid molecule consisting of SEQ ID NO: 3.

Applicant is not in possession of: an isolated nucleic acid molecule comprising a **portion of SEQ ID NO: 3**, wherein **said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene**, and wherein said nucleic acid molecule **comprises a mutant allele of said GK gene at said nucleotide position 29** of claim 1; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule **comprises a portion of SEQ ID NO: 3**, wherein **said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene**, and wherein said nucleic acid molecule comprises **a mutant allele of said GK gene at said nucleotide position 29** of claim 2; The nucleic acid molecule of claim 1, wherein **said portion is at least 20 nucleotides in length** of claim 3; The nucleic acid molecule of claim 1, wherein **said portion is at least 50 nucleotides in length** of claim 4; The nucleic acid molecule of claim 1, wherein said mutant allele **comprises a nucleotide selected from the group consisting of a guanosine, a thymidine, and a cytidine at said nucleotide position 29** of claim 5; The nucleic acid molecule of claim 5, wherein said nucleic acid molecule comprises a **guanosine at said nucleotide position 29** of claim 6; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and **polypeptide nucleic acid (PNA)** of claim 7; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule comprises a label of claim 8; The nucleic acid molecule of claim 8, wherein the label is selected

from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 9; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is immobilized on a solid support of claim 10; The nucleic acid molecule of claim 10, wherein the nucleic acid molecule is one of an array of **two or more different nucleic acid molecules** immobilized on said solid support of claim 11; An isolated nucleic acid molecule **comprising** SEQ ID NO: 3, wherein said nucleic acid molecule **comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene** of claim 12; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule **comprises SEQ ID NO: 3**, wherein said nucleic acid molecule **comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene** of claim 13; The nucleic acid molecule of claim 12, wherein said nucleic acid molecule is at least 250 nucleotides in length of claim 14; The nucleic acid molecule of claim 12, wherein said mutant allele comprises a nucleotide selected from the group consisting **of a guanosine, a thymidine, and a cytidine at said nucleotide position 29** of claim 15; The nucleic acid molecule of claim 15, wherein said nucleic acid molecule comprises **a guanosine at said nucleotide position 29** of claim 16; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and **polypeptide nucleic acid (PNA)** of claim 17; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule comprises a label of claim 18; The nucleic acid molecule of claim 18, wherein the label is selected from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 19; The nucleic acid molecule of claim 12, wherein the nucleic acid molecule is immobilized on a solid support of claim 20; The nucleic acid molecule of claim 20, wherein the nucleic acid molecule is one of an array of **two or more**

different nucleic acid molecules immobilized on said solid support of claim 21; An isolated nucleic acid molecule which **specifically hybridizes to a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon l0 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29** of claim 22; An isolated nucleic acid molecule consisting of **a portion of SEQ ID NO: 3**, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 of claim 23; and An isolated nucleic acid molecule consisting of SEQ ID NO: 3, wherein said nucleic acid molecule comprises a mutant allele at nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene at said nucleotide position 29 of claim 24.

The specification describes only a single nucleic acid sequence consisting of SEQ ID NO:3 for use in the claimed invention.; therefore, the skilled artisan cannot envision all the contemplated nucleic acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description"

Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-2, 5-10 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,583,275 (PTO-892, Reference A).

U.S. Patent 6,583,275 teaches an isolated nucleic acid molecule comprising a portion of SEQ ID NO: 3, wherein said portion is 19 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 (G) of claim 1 (In particular, reference SEQ ID NO:2884 comprises nucleotides 34-52 of instant SEQ ID NO:3, corresponding to positions 910-928 of SEQ ID NO 2884, wherein nucleotide 51 is mutated to G; See Attachment I) ; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule comprises a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide

position 29 of claim 2; The nucleic acid molecule of claim 1, wherein said mutant allele comprises a nucleotide selected from the group consisting of a guanosine, a thymidine, and a cytidine at said nucleotide position 29 of claim 5; The nucleic acid molecule of claim 5, wherein said nucleic acid molecule comprises a guanosine at said nucleotide position 29 of claim 6; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and polypeptide nucleic acid (PNA) of claim 7; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule comprises a label of claim 8 (In particular, column 11, lines 50-57); The nucleic acid molecule of claim 8, wherein the label is selected from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 9 (In particular, column 11, lines 50-57); The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is immobilized on a solid support of claim 10 (In particular, column 11, lines 57-63); and An isolated nucleic acid molecule which specifically hybridizes to a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon l0 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 of claim 22.

The prior art teachings anticipate the claimed invention.

12. Claims 1-2, 5-9 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,272,078 (PTO-892, Reference B).

U.S. Patent 5,272,078 teaches an isolated nucleic acid molecule comprising a portion of SEQ ID NO: 3, wherein said portion is 14 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 (G) of claim 1 (In particular, Figure 1 comprises nucleotides 45-58 of instant SEQ ID NO:3, corresponding to positions 654-667 in Reference Figure 1, wherein nucleotide 51 is mutated to G; See Attachment II) ; A complement strand of a nucleic acid molecule, wherein said nucleic acid molecule comprises a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase (GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 of claim 2; The nucleic acid molecule of claim 1, wherein said mutant allele comprises a nucleotide selected from the group consisting of a guanosine, a thymidine, and a cytidine at said nucleotide position 29 of claim 5; The nucleic acid molecule of claim 5, wherein said nucleic acid molecule comprises a guanosine at said nucleotide position 29 of claim 6; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule is selected from the group consisting of DNA, RNA, and polypeptide nucleic acid (PNA) of claim 7; The nucleic acid molecule of claim 1, wherein the nucleic acid molecule comprises a label of claim 8 (In particular, column 13, line 48 to column 14, line 7); The nucleic acid molecule of claim 8, wherein the label is selected from the group consisting of a radioisotope, a fluorescent compound, an enzyme, and an enzyme cofactor of claim 9 (In particular, column 13, line 48 to column 15, line 7); and an isolated nucleic acid molecule which specifically hybridizes to a portion of SEQ ID NO: 3, wherein said portion is at least 10 nucleotides in length and includes nucleotide position 29 of exon 10 of a glycerol kinase

(GK) gene, and wherein said nucleic acid molecule comprises a mutant allele of said GK gene at said nucleotide position 29 of claim 22.

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent 6, 583,275 (PTO-892, Reference A) or U. S. Patent 5,272,078 (PTO-892, Reference B) each in view of U. S. Patent 5,837, 860 (PTO-892, Reference C).

U. S. Patent 6, 583,275 and U. S. Patent 5,272,078 have been discussed supra.

The claimed invention differs from the prior art by the recitation of wherein the nucleic acid molecule is immobilized onto a solid support (as applied to U.S. Patent 5, 272, 078 only) and wherein the nucleic acid molecule is one of an array of two or more different nucleic acids molecules immobilized onto said solid support.

U.S. Patent 5, 837,860 teaches that the analysis of the structure, organization and sequence of nucleic acid molecules is of profound importance in the prediction, diagnosis and treatment of human and animal disease, in forensics, in epidemiology and public health, and in the elucidation of the factors that control gene expression and development and that methods for immobilizing nucleic acids are often important in these types of analyses. (In particular, 'Background of the Invention' section, whole document) The analysis of genomic polymorphisms is of particular importance. The '860 Patent teaches a method to covalently couple nucleic acid molecules to a solid-phase by means of reversible disulfide bond interactions. The immobilized molecules can be used for hybridization, sequencing, or polymorphic analysis (in particular, 'Summary of the Invention' section, whole document).

It would be obvious to one of ordinary skill in the art to use the reference nucleic acid in an array of two or more nucleic acids immobilized onto a solid support because the '860 patent teaches that the method of using nucleic acids attached to arrays is useful for diagnosis of genetic polymorphisms and disease. It would be obvious to couple the reference nucleic acid onto an array with another nucleic acid to diagnose more than one genetic polymorphism or disease at the same time.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER
TC 1600

August 17, 2007

Nora Rooney

Attachment I

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RESULT 9
US-09-107-532A-2884
; Sequence 2884, Application US/09107532A
; Patent No. 6583275
;   GENERAL INFORMATION:
;        APPLICANT: Lynn A Doucette-Stamm  and David Bush
;        TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES
RELATING TO
;                                ENTEROCOCCUS FAECIUM FOR DIAGNOSTICS AND
THERAPEUTICS
;        NUMBER OF SEQUENCES: 7310
;        CORRESPONDENCE ADDRESS:
;             ADDRESSEE: GENOME THERAPEUTICS CORPORATION
;             STREET: 100 Beaver Street
;             CITY: Waltham
;             STATE: Massachusetts
;             COUNTRY: USA
;             ZIP: 02354
;        COMPUTER READABLE FORM:
;             MEDIUM TYPE: CD/ROM ISO9660
;             COMPUTER: PC
;             OPERATING SYSTEM: <Unknown>
;             SOFTWARE: ASCII
;        CURRENT APPLICATION DATA:
;             APPLICATION NUMBER: US/09/107,532A
;             FILING DATE: 30-Jun-1998
;        PRIOR APPLICATION DATA:
;             APPLICATION NUMBER: 60/085,598
;             FILING DATE: 14 May 1998
;             APPLICATION NUMBER: 60/051571
;             FILING DATE: July 2, 1997
;        ATTORNEY/AGENT INFORMATION:
;             NAME: Ariniello, Pamela Deneke
;             REGISTRATION NUMBER: 40,489
;             REFERENCE/DOCKET NUMBER: GTC-012
;        TELECOMMUNICATION INFORMATION:
;             TELEPHONE: (781)893-5007
;             TELEFAX: (781)893-8277
;   INFORMATION FOR SEQ ID NO: 2884:
;        SEQUENCE CHARACTERISTICS:
;             LENGTH: 2367 base pairs
;             TYPE: nucleic acid
;             STRANDEDNESS: double
;             TOPOLOGY: circular
;        MOLECULE TYPE: DNA (genomic)
;        HYPOTHETICAL: NO
;        ANTI-SENSE: NO
;        ORIGINAL SOURCE:
;             ORGANISM: Enterococcus faecium
;        FEATURE:
;             NAME/KEY:  misc_feature
;             LOCATION: (B) LOCATION 1...2367
;        SEQUENCE DESCRIPTION: SEQ ID NO: 2884:
US-09-107-532A-2884

  Query Match           20.2%;  Score 19;  DB 3;  Length 2367;
  Best Local Similarity  100.0%;  Pred. No. 2.6;
  Matches   19;  Conservative    0;  Mismatches    0;  Indels    0;
Gaps    0;

Qy         34 GATGTTTCTTACTATGTGA 52
              ||||||||||||||||||
Db        910 GATGTTTCTTACTATGTGA 928
```

CC reporter genes based on the human gene sequence containing Cys in place
CC of selenocysteine, may be used for monitoring transfection efficiencies
CC or in the study of heterologous promoter function in transient expression
CC assays. Characterisation of the selenocysteine insertion sequence is
CC useful to effect incorporation of selenocysteine into peptides or
CC proteins to study the effects of the presence of selenocysteine on the
CC properties of such proteins (see also AAQ53466-68). (Updated on 25-MAR-
CC 2003 to correct PF field.)
XX
SQ Sequence 2106 BP; 523 A; 527 C; 512 G; 544 T; 0 U; 0 Other;

Query Match 73.7%; Score 14; DB 2; Length 2106;
Best Local Similarity 100.0%; Pred. No. 1e+02;
Matches 14; Conservative 0; Mismatches 0; Indels 0;
Gaps 0;

Qy 4 CTATGTGATACAGG 17
||||||||||||||
Db 654 CTATGTGATACAGG 667